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Working Group Report

Creating innovative departments☆

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Summary

'Creating an innovative department' as an objective implies further improvements in organization, function, and progression of a surgical unit active in patient care, research, and education. It is of prime importance to stress here the mutual benefits of patient care, research (the basis for future patient care) and education (the channel for training health care professionals in future patient care). Neither innovation (from latin innovare: to renew, revive) nor creation (from latin creare: to make, produce) is something that will fall from heaven without effort any time soon. Hence, a pro-active attitude towards progress is indicated. This requires searching for new ideas, allocation of resources, finding allies, getting focussed, and being persistent. One word says it all: WORK!

Keywords: Thoracic- and cardio-vascular surgery; Organization; Innovation; Future

1. Introduction

Tremendous success, exaggerated safety concerns, over-regulation, and lack of interest among other developments have led to a situation in many departments, where enthusiasm has evaporated, stagnation is taking over, and worse, regression has arrived. As a matter of fact, percutaneous procedures have seen a much stronger development (2.3 times higher caseload in Switzerland by now) than traditional coronary artery bypass grafting [1], and this despite proven superior results with arterial conduits [2], and the efforts made for reduction of pump related events with off-pump techniques [3].

2. General developments

However, such a development is not specific for the cardio-vascular field or medicine, and is rather the rule for many fields. Nowadays, endoscopes are used routinely for inspection of the combustion chamber in Otto or Diesel engines, despite the fact that the surfaces of interest can also be visualized if the cylinder heads are removed. Likewise, obstructed or leaking drain pipes can be inspected and even repaired with robotic systems, thus avoiding major road works and the consecutive traffic jam. Neither the construction companies, nor manufacturers of earth moving equipment (e.g. Caterpillar, Liebherr, Komatsu) nor car repair shops have disappeared. What has changed are mobility and speed of communication, which in turn require accelerated search of new opportunities and the corresponding adaptation of both human resources and infrastructure.

3. Specific developments

Not all surgical disciplines have managed such changes with equal success, but some have done this very well. The urologists, who emerged from general surgery have successfully managed the transition from open surgery to endoscopic treatments and even percutaneous procedures. But not only that, the urologists have also been able to maintain a significant stake in the entire value chain from diagnostics (e.g. ultrasound), to patient work-up (e.g. cystoscopy, ureteroscopy, biopsy, pyelography), treatment (e.g. transurethral resection, shock wave lithotrypsy), and follow-up (e.g. instillation of anti-mitotic drugs).

We are far away from having solved all cardio-vascular and pulmonary problems, and therefore, thoracic and cardio-vascular surgery has a huge potential for further development, provided we are willing to stay involved. Although the main characteristic of surgery is 'manual operation' as the original Greek term translates to, its enhancement with technology multiplies its potential (e.g. automated CPR, CPS, VAD, TAH). Of course, there are not only technological hurdles to overcome in order to make significant progress. A number of concerns in our context and potential answers are listed in Table 1.

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Table 1
Food for thought proposed at the Symposium for the Future

- Products have a live (birth, growth, death)
  The same holds true for treatment strategies and procedures (e.g. MIDCAB)
- Change is everywhere
  Change implies problems and opportunities (e.g. merging programs)
- Innovation versus stagnation
  Our attitude is our responsibility
- Activities should include clinical work, research, and teaching
  Resources have to be allocated accordingly
- Regulations kill innovation
  Organizations should refrain from ruling everything
- Working hours should be unlimited
  Competition cannot be forbidden
- Off-hours science clubs may be an answer
  If golf is ok, what about virtual perfusion
- Growth can be qualitative and quantitative
  Not all specialities have abandoned diagnostics
- Volume can be achieved by specialization or generalization
  Bentall procedure, mini-root aortic valve replacement, valve preserving aortic root repair, Ross procedure, and arterial switch are all the same
- Cooperations can be institutional, regional, national and international
  There are no limits to tele-consulting, tele-medicine, and tele-monitoring between doctors, scientists, patients, etc.

4. Views of the working group

During this meeting, the working group in charge 'Creating Innovative Departments' devised a series of statements, which are displayed in Tables 2–5. With regard to the status quo, increasing competition appeared to be of major concern for Western Europe, due to a still increasing number of thoracic and cardio-vascular surgical units and a decreasing number of cases (Table 2), surgical cases of course. As we have seen earlier, the number of patients treated for coronary artery disease is still increasing, but in other departments. Likewise, there is still growth in surgical units in Eastern Europe and even more so in other geographical zones. Many participants, perceived the developments in Western Europe just described as a major threat at the level of the units, as well as at the level of the individuals involved (Table 3). However, a number of opportunities were also identified (Table 4). On top of the search for improved and new activities, ranks the pivotal role of the European Association for Cardio-thoracic Surgery as an instrument for promotion of big trials showing the true value of surgical approaches. Table 5 lists the required actions for strengthening thoracic and cardio-vascular surgery in general as well as its individual units.

5. Comment

It has to be mentioned here, that the development and implementation of new ideas, new procedures, new technology, and new solutions needs not only an open mind [4], but at least as much perseverance to reach the so-called 'break through'. Personally, I am increasingly convinced that the discovery of a new procedure, or a major break-through by a stroke of luck is the very, very exception, and that the main steps forwards have usually been achieved on the basis of long and hard work. This is by no means a new discovery but has always been like that, as the following few examples may illustrate.

It took the polish astronomer Copernicus a long time, perhaps 30 years [5], to produce and publish in 1543 the epoch-making *Rinensis de revulutionibus orbium coelestium* [6] describing the planetary helio-centric system, and even more time was necessary to have his cosmology accepted [7].

A personality much closer to our activities is certainly Vincent L. Gott, who made pivotal contributions to the development of cardio-vascular implants produced from synthetic materials with improved thromboresistance [8]. Although he describes a series of serendipitous events that lead the way to bond heparin, using a coating of graphite-carbon and benzalkonium-chloride, it was the fact that HE was WORKING in this field, that made his discoveries possible. Again it took about 30 years from the description of the principles in the 1960s [9] to ubiquitous clinical application: heparin coatings for cardiopulmonary bypass components [10], catheters, as well as assist devices, or carbon coatings for prosthetic heart valves.

The development of disruptive technology is a dream, which haunts quite some people as pointed out by J.C. Dvorak in his column in PC-Magazine [11]. The theory goes, that a new cheaper technology gains some foothold, continues to improve, and then quickly bumps the older, once superior technology. For our field of activities we now

Table 2
View of the working group: status quo

- Number of centers increase
- Number of cases decrease
- More competition results

Table 3
View of the working group: potential threats

- Loss of access to patients
- Loss of income
- Loss of support for research
- Loss of training opportunities
- Loss of …

Table 4
View of the working group: opportunities

- Develop new activities
- Cooperate with other societies
- Make EACTS meeting the largest event
- Create EACTS Research Center for big trials

Table 5
View of the working group: actions

- Search, innovate
- Restructure, optimise
- Invest
- Focus
- Network
- Communicate
- Market

Table 6
Pro-active approach in a nut-shell

Evolution	Accept change
Activation	Hunt for ideas
Commitment	Allocate resources
Momentum	Convince allies
Focus	Do not get distracted
Perseverance	Do not give up

are looking over 50 years for e.g. a new cheaper mechanical heart valve prosthesis, which does not need anticoagulation—without luck, so far. Dvorak lists a number of so-called disruptive technologies, which in fact are not, like digital photography. As a matter of fact digital photography has never been cheaper than film—and it has been introduced in 1972, more than 30 years ago (for more: www.pcmag.com/dvorak).

'Creating an innovative department' as an objective implies further improvements in organization, function, and progression of a surgical unit active in patient care, research, and education. It is of prime importance to stress here the mutual benefits of patient care, research (the basis for future patient care) and education (the channel for training health care professionals in future patient care). Neither innovation (from latin innovare: to renew, revive) nor creation (from latin creare: to make, produce) is something that will fall from heaven without effort any time soon. Hence, a pro-active attitude towards progress (Table 6) is indicated. In accordance to the first book printed ever, on the seventh day, God rested from all his work, which he had done in creation [12]. Hence, for the more ordinary mortals among us, there can be only one rational approach to create innovative departments: WORK!

References

[1] Bruckenberger E. Herzbericht 2002. 15. Bericht der Arbeitsgruppe Krankenhauswesen der Arbeitsgemeinschaft der obersten Landesgesundheitsbehörden der Länder (AOLG). Hannover 2003:150.
[2] Muneretto C, Negri A, Bisleri G, Manfredi J, Terrini A, Metra M, Nodari S, Dei Cas L. Is total arterial myocardial revascularization with composite grafts a safe and useful procedure in the elderly? Eur J Cardiothorac Surg 2003;23:657–64.
[3] Biglioli P, Cannata A, Alamanni F, Naliato M, Porqueddu M, Zanobini M, Tremoli E, Parolari A. Biological effects of off-pump versus on-pump coronary artery surgery: focus on inflammation, hemostasis, and oxidative stress. Eur J Cardiothorac Surg 2003;24:260–9.
[4] von Segesser LK. Surgical technique versus technology for surgery: a plea for an open mind towards new technology. Interact Cardiovasc Thorac Surg 2002;1:1–3.
[5] Barker P. A history recorded in the margins. Science 2004;304:686.
[6] Copernicito N. Rinensis de revolutionibus orbium coelestium. Johann Petreius, Nuremberg 1543.
[7] Gingrich O. The book nobody read. New York: Walker; 2004.
[8] Gott VL, Daggett RL. Serendipity and the development of heparin and carbon surfaces. Ann Thorac Surg 1999;68:S19–S22.
[9] Gott VL, Whiffen JD, Dutton RC. Heparin bonding on colloidal graphite surfaces. Science 1963;142:1297–8.
[10] von Segesser LK. Safety and efficacy of heparin bonded surfaces in cardiopulmonary bypass. J Thorac Cardiovasc Surg 2001;121:200–1.
[11] Dvorak JC. The myth of disruptive technology. PC-Magazine 2004;23(14):55.
[12] Piscator J. Biblia, Genesis II/1. A. Hügener, Bärn 1684:2.

Appendix. Conference discussion

Dr A. Kappetein (*Rotterdam, Netherlands*): I very much like the idea of setting up a research center sponsored by the European Association, but what we should not forget is that if you want to run a trial by the Association, it costs a lot of money. The SynTax trial which we were talking about costs around $20 million, and the Expedition trial costed about $80 million. So trials are too expensive to be sponsored by the European Association. But what you could do is, support observational studies. These are sometimes as powerful important, as Axel Haverich pointed out, as trials. There is an interesting study in the New England Journal of Medicine that showed that observational studies in many instances have the same outcome, as randomized trials. We could as the European Association, for example, support registries for Ross operations, aortic valve replacements, new techniques in coronary surgery, and aortic stenting, and in this way you could collect data from many centers and you will have much more power if you publish it because you have a large number of data.

Dr von Segesser: The Association is already sponsoring a number of databases, and if we say, for instance, we want to know the data of, let's say, OPCAB on the circumflex artery, I think it should not be so difficult to have our members fill in some forms, to collect these forms, and even pay 100 Euros per form; 1000 patients costs 100,000 Euros. That is not impossible for an Association like ours.

So although we know that industry-sponsored studies may bring some money into the unit, here we are talking about if our units are going to exist, and maybe it is worth to put in some manpower to get the data we need.

Dr Kappetein: I agree. I think every unit has some money to have a research nurse or to set up a database, and it is not so difficult to provide data from observational studies. That is not very costly and in that way we could easily share these data.

Dr D. Birnbaum (*Regensburg, Germany*): Pieter (Pieter Kappetein), you probably read my ideas. I just wanted to say almost the same, but I would like to add a few things.

The aim of the Association is to support science, it is a scientific society. Therefore I believe that the Association must find ways to support research. Research today costs a lot of money, and I am not convinced that the Association can pay for trials such as biostatistical powered and following all the rules, which hold for an accepted study as standard. But there are ways such as fund-raising, and I think this Association could have the possibility to raise funds Europe-wide. There are even institutions who do nothing else but fund-raising as their obligation. They share the money by raising funds for an Association like this one.

Furthermore I believe that the Association could support data registration in a form of either work together with an enterprise, which is able to do trials in a professional way. They don't want too much money, but I think a contract with them gives the possibility to maintain qualitatively good research and to help such an institution. Alternatively the commitment of clinical researchers to follow the consensus for a data acquisitation should make it possible to search for important single questions. The council should deal with these possibilities and come to a recommendation how the Association will orient on this need for research, research in the field of clinical studies, of trials, of observational studies, and of registries. It is a necessity to have large registries such that the Association has some sort of control of what is going on in the field of clinical research. By this kind of support the initiator or study leader will feel protected for negative judgments of negative results or of expectances of the public if the Association stands behind such a trial.

I think that the Association needs to find ways how to support this intention to increase research activity. Otherwise we are stuck on individualized activities, and I think this is not good, because all sorts of discrepancies then will continue to bias these studies.

Mr B. Keogh (*Birmingham, UK*): Perhaps I could just say something about where we are heading on the registry front. As you know, last year we published a very slim and early version of an EACTS database report, which will be slightly less slim this year in the sense that there will be more data in from two additional countries. The strategy we had taken was that EACTS would try and help individual nations collect their own data, because there has to be ownership of that data, and probably the best way in the longer term is to have that ownership at a national level and merging it at a supranational

level. So we have it in mind to apply for a European Union grant to try and spread that out across the European Union, and within that grant, to include at least one person for each of the contributing national societies. If it is an EACTS-sponsored grant, we could explore what the job description of that person.

Dr S. Hagl (*Heidelberg, Germany*): I fully support what Pieter just said, but I think if we want to reach a real acceptable scientific level, it is not sufficient to have only registries, to have studies. You also have to have the instruments to control that these registries and these studies are really getting valid data, and that is a difficult problem.

In Germany several registries have started. The outcome was highly disappointing: only a part of procedures were registered, we didn't know what happened to the others, we had no instruments to control it. So what I wanted to say is, it is not sufficient to have this only, but to have an instrument, an apparatus behind it, which is really making out of such registries and out of such data scientifically valuable information.

Mr Keogh: Siegfried (Siegfried Hagl), may I just bounce a proposal off people? It is quite clear that as an Association we can't afford the sort of money that is required for the sort of solid scientific research and clinical trials that you are talking about. The one thing that might be helpful, and we could see what Bob (Robert Guezuraga) has to say about this, is we could put out the message that EACTS might be interested, for example, in sponsoring or kite-marking research, and that might encourage people who want to undertake new research, albeit commercially funded or otherwise, to approach the Association. If such a kite mark were to be applied it would immediately give enormous credibility to any study that was proposed. But the price that would have to be paid for that kite mark is intimate involvement of, let's say, a clinical trials group or a research committee in the design and, most importantly, the analysis and publication of those results. And that way I think we could have significant influence on how the research is conducted without necessarily the financial commitment that would be needed to conduct it on our own.

You may feel that that is not a good option. How would you respond to something like that, Bob?

Mr R. Guezuraga (*Minneapolis, Minnesota*): I would be positive, and I think industry would be positive. The basic research, research that leads to product, and people don't get very comfortable with this, but when industry does research that leads to product, industry then wants the rights to that product, or at least to share the rights for that product, because it's going to be commercialized, that would be sort of the general direction as to where industry would want to do some funding.

Mr Keogh: We would be more interested in ensuring scientific integrity of the study.

Mr Guezuraga: In the sense that you want to have something published, and this happens all the time, the right to publish belongs to the person who did the work. Now, I wouldn't want to fund externally a technology that I have a high level of interest in, and also, I would need to have a high level of confidence that it was obviously going to turn out to the positive. But, if it doesn't, it doesn't. We have funded studies, large-scale studies in Medtronic businesses, that have produced poor results, and we just move on as a consequence of it. Hopefully, it is an investment; it is not just throwing out money.

Mr Keogh: How much value commercially is sponsorship from an organization of this size to a study that you might be conducting? Are you interested in that or is it too big a risk?

Mr Guezuraga: I will give you an example of a study. It would be in the area of atrial fibrillation. All the manufacturers have devices that ablate tissue, but in the United States it is the only claim that can be made. So studies have to be done that these are devices that can do cardiac ablation, and therefore those are the claims that are marketed once those claims are submitted to the regulatory body and then are approved. So that would be an interesting study.

Dr Hagl: Bruce (Bruce Keogh), if I may, I would like to add another point, it was already discussed, and that is the point when we start to introduce innovation into the clinics. What we are doing at the moment, or let's say if we look in the past, it was more or less uncontrolled, as we know. Everybody took an instrument or a new device created by the industry and implanted it and we never got results and exact and valid information how this new device is really performing under clinical conditions. So I think it would be a very important task for the European Association to control that in the future, perhaps in cooperation with industry so that we get real information about what happens and in what respect we can trust a new device. And it is not sufficient, I say it again, it is not sufficient to have a registry, because nobody is controlling that.

Dr von Segesser: So you are saying that we need an auditing body that checks out what has been documented?

Dr Hagl: I think we can forget about all the studies, all the registries if we are not consequently really controlling what happens, because I believe nobody in that respect.

Dr von Segesser: So one of the ideas would be to establish an auditing body like, for instance, the cancer people have. They have an organization; you can organize a study, they bring in the study nurses. Of course, it costs something. But I am not so sure about the statement that the EACTS cannot afford something like that, because if you need 10,000 patients to show that your approach is marginally better than the other one, it means that there is no difference, and there are still topics around where you can do something with 100 or 200 patients, and I think small trials, to start with, EACTS could support.

Mr Keogh: That just highlights the need for clinical trials or an equivalent group to start thinking about these things, doesn't it?